Paper No. 20

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DIRKJAN BAKKER, JOHANNES J. GROTE,
and CLEMENS A. VAN BLITTERSWIJK

Appeal No. 1996-3547
Application No. 08/089,854[1]

ON BRIEF

Before PAK, OWENS, and KRATZ, Administrative Patent Judges.

KRATZ, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's refusal to allow claims 13-19 and 68-107, which are all of the claims pending in this application.

[1] Application for patent filed July 21, 1993. According to appellants, this application is a continuation-in-part of Application 07/907,674, filed July 2, 1992, now abandoned; which is a continuation-in-part of Application 07/479,197, filed February 13, 1990, now abandoned; which is a continuation-in-part of Application 07/240,810, filed September 2, 1988, now abandoned.

BACKGROUND

The appellants' invention relates to a prosthetic device useful for binding to bone. An understanding of the invention can be derived from a reading of exemplary claims 68, 106 and 107, which are reproduced below.

68. A prosthetic device for binding to bone, said prosthetic device having a shape suitable for placing the prosthetic device in contact with bone for binding to bone, said prosthetic device comprising a polymer, said polymer being a segmented thermoplastic polymer comprising a plurality of recurring units of a first component and of a second component, wherein said first component comprises units having the formula:

-OLO-CO-R-CO-, wherein L is selected from the group consisting of: (i) a divalent radical remaining after removal of terminal hydroxyl groups from a poly(oxyalkylene) glycol; and (ii) a polymer including a first moiety and a second moiety, said first moiety being a polyalkylene glycol and said second moiety being selected from the group consisting of glycine anhydride, alloxan, uracil, 5,6-dihydrouracil, glycolic acid, lactic acid, and lactones, and R is a divalent radical remaining after removal of carboxyl groups from a dicarboxylic acid, and said second component comprises units having the formula:

-OEO-CO-R-CO,

wherein E is an alkylene radical, and R is a divalent radical remaining after removal of carboxyl groups from a dicarboxylic acid.

106. A prosthetic for binding to bone, said prosthetic device having a shape suitable for placing the prosthetic device in contact with bone for binding to bone, said prosthetic device comprising a polymer, said prosthetic device selected from the group consisting of: (a) a covering of middle ear bones; (b) an artificial ossicle; (c) an artificial palate; (d) a sinus ventilation tube; (e) an orthopedic implant coated with said polymer; (f) a distal portion of a hip stem; (g) a mastoid repair device; (h) an ear canal wall; (i) a closure of the nasal septum;

(j) a bone augmentation device employed in maxillofacial surgery; (k) a preformed mandible; (l) a skull augmentation; (m) a periodontal ligament replacement; (n) an osteotomy spacer; (o) a dental ridge augmentation; (p) a fracture fixation; (q) a spinal fusion device; (r) an artificial dowel; (s) a spinal fixation; (t) a disk; (u) an artificial ligament; (v) a device employed in interstitial cartilage repair or replacement; (w) an anchor element for ligament repair; (x) a swell fixation; (y) a Hercules plug; (z) a bone filler; (aa) a cartilage sheet; (bb) a fracture bandage for treating a compound fracture; (cc) a skull fixation; (dd) a burr hole plug; (ee) a tooth coated with said polymer; (ff) a dental sheet; (gg) a dental implant coated with said polymer; (hh) a bone dressing; and (ii) an artificial joint coated with said polymer, said polymer being a polyethylene glycol/polybutylene terphthalate segmented copolymer.

107. A prosthetic device for binding to bone said prosthetic device having a shape suitable for placing the prosthetic device in contact with bone for binding to bone, said prosthetic device comprising a polymer having a porous surface, said porous surface containing pores at least a portion of which have a pore diameter of from 50 to 500 microns, said polymer being a segmented thermoplastic polymer comprising a plurality of recurring units of a first component and of a second component, wherein said first component comprises units having the formula:

-OLO-CO-R-CO-, wherein L a divalent radical remaining after removal of terminal hydroxyl groups from a poly (oxyalkylene) glycol, and R is a divalent radical remaining after removal of carboxyl groups from a dicarboxylic acid, and said second component comprises units of the formula:

-OEO-CO-R-CO,

wherein E is an alkylene radical; and R is a divalent radical remaining after removal of carboxyl groups from a dicarboxylic acid.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Jones et al. (Jones) 3,908,201 Sep. 30, 1975

Spector et al. (Spector) 4,164,794 Aug. 21, 1979

Claims 71-106 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as their invention. Claims 13-19 and 68-106 stand rejected under 35 U.S.C. § 102(b) as anticipated by Jones or, in the alternative, under 35 U.S.C. § 103 as being unpatentable over Jones. Claim 107 stands rejected under 35 U.S.C. § 103 as being unpatentable over Jones in view of Spector.

OPINION

We refer to the appellants' brief and to the answer for the opposing viewpoints expressed by the appellants and the examiner concerning the above noted rejections. For the reasons which follow, we cannot sustain the examiner's stated § 112, second paragraph, rejection. However, we shall sustain the examiner's §§ 102 and 103 rejections as expressed in the answer for reasons as further explained below.

Rejection under 35 U.S.C. § 112, second paragraph

The relevant inquiry under 35 U.S.C. § 112, second paragraph, is whether the claim language, as it would have been interpreted by one of ordinary skill in the art in light of appellants' specification and the prior art, sets out and

circumscribes a particular area with a reasonable degree of precision and particularity. See In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971).

In rejecting claims 71-106 under 35 U.S.C. § 112, second paragraph, the examiner (answer, page 3) urges that "it is unclear how the intended use terminology is intended to modify the claim language" so as to further limit the invention. At page 7 of the answer, the examiner further explains that "it would be difficult to determine the scope of the claims because the terminology is based on a use rather than on actual structure." While we recognize that the variously recited functional potential use limitations of these claims do not circumscribe a narrowly defined shape for the prosthetic device, such breadth does not equate with indefiniteness. *See In re Gardner*, 427 F.2d 786, 788, 166 USPQ 138, 140 (CCPA 1970). From our reading of appellants' specification, including the claims, and the relevant prior art, it is clear that the prosthetic device shape called for in claims 71-106 is reasonably definite albeit broad in encompassing any suitable shape that would be useful for the suggested applications. Accordingly, we shall not sustain the examiner's rejection of claims 71-106 under 35 U.S.C. § 112, second paragraph.

As an additional matter and to the extent the examiner's rejection of dependent claims 71-105 may have been premised on their purported failure to further limit the claim(s) from which they depend, we note that issues regarding whether or not a dependent claim further limits a claim from which it depends are appropriately addressed under 35 U.S.C. § 112, paragraph 4. We hasten to add at this juncture that we do not find, nor has the examiner furnished, an adequate factual basis and reasoning to support such a possible 35 U.S.C. § 112, fourth paragraph, inquiry.

Rejection under 35 U.S.C. § 102/103 over Jones

Initially, we note that appellants state "the rejected claims do not stand or fall together" (brief, page 4). However, we note that appellants do not separately argue claims 13-19 and 68-70 and the arguments regarding claims 71-106 are not sufficiently specific to be consistent with 37 CFR § 1.192 (c)(7) and (8) (1995) to warrant their separate consideration. In this regard, merely pointing out differences in the coverage of the claims does not amount to a separate argument warranting separate consideration of the claims (brief, page 7). Accordingly, for purposes of this rejection, we consider all of the claims to stand or fall together. See *In re Nielson*, 816 F.2d 1567, 1572,

2 USPQ2d 1525, 1528 (Fed. Cir. 1987); *In re Kaslow*, 707 F.2d 1366, 1376, 217 USPQ 1089, 1096 (Fed. Cir. 1983). We will direct our comments primarily to claim 68.

Jones discloses a prosthetic device comprising a plastic material including a first polyether component such as poly(ethylene glycol) and a second water stabilizing component such as an ester, urethane or amide. Appellants do not specifically dispute the examiner's finding (answer, page 4) that the polymers disclosed for use in fashioning the prosthetic device of Jones (U.S. patent No. 3,908,201) fully meet the polymer material utilized in the claimed prosthetic device.[2]

Appellants urge that the claimed subject matter is patentably distinguished from Jones based on the claimed functional limitation requiring the device to be "suitable for placing the prosthetic device in contact with bone" (claim 68). According to appellants, this functional limitation limits the device to a particular shape and wherein the device has bone bonding capabilities (brief, pages 4-8). We disagree.

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[2] We note that appellants have indicated that their "...copolymers may be prepared as described in U.S. Patent No. 3,908,201" (specification, page 8). Moreover, appellants have acknowledged that the claimed copolymers "... are known in the art..." (brief, page 3).

Based on the present record, it is our view that the claimed prosthetic device shape encompasses the prosthetic device shapes as disclosed in Jones. In this regard, we note that during patent examination the Patent and Trademark Office gives the language of the claims the broadest reasonable interpretation consistent with the specification and the prior art. *See, e.g., In re Graves*, 69 F.3d 1147, 1151, 36 USPQ2d 1697, 1700 (Fed. Cir. 1995). Here, the specification on page 16 indicates that:

> The shape of the prosthetic devices may vary considerably, depending upon the particular application. Examples of shapes include, but are not limited to, films, woven and nonwoven sheets, plates, screws, filaments for wrapping injured or fragmented bones, staples, "K" wire, and spinal cages.

Moreover, a wide variety of applications are encompassed by the claims as evidenced by the exemplary non-exclusive list of applications furnished in the specification (carryover paragraph, pages 15 and 16) and as variously recited in some of the appealed claims. Thus, we determine that the claimed functional limitation "suitable for placing the prosthetic device in contact with bone for binding to bone" (claims 68, 70 and 106) encompasses any shape device capable of being placed in contact with bone. Jones clearly teaches such a prosthetic device. In this regard, we note that the prosthetic devices of Jones are

shaped so as to be suitable for use in a human or animal body, as a cosmetic nose implant, for example (column 2, lines 33-40). Moreover, Jones specifically discloses a disc shape (Example 4, for example) that is sized for implantation in the back of a rat. Compare Jones with, e.g. claim 90 reciting a disk.

Where, as here, there is a reasonable basis to believe that the critical function (suitable for bone contact and binding) that is alleged to establish novelty in the claimed subject matter is, in fact, a characteristic of the prior art device as urged by the examiner, it is incumbent upon appellants to prove that the prior art device does not in fact possess the characteristics relied on. *See, e.g., In re Schreiber*, 128 F.3d 1473, 1478, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997)*; In re Spada*, 911 F.2d 705, 708-09, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The present record is devoid of such proof.

In light of the above, we determine that the examiner has established that the subject matter of claims 13-19 and 68-106 is unpatentable under 35 U.S.C. § 102/§ 103.

In addition, we agree with the examiner that even if the claimed prosthetic device differs from the device of Jones by virtue of the claimed functional language, a skilled artisan would have found the fashioning of a bone binding shape for the

prosthetic device of Jones to have been an obvious modification within the skill of the art because the teachings of Jones regarding the moldability and collagenous material binding properties of the prosthetic materials would have suggested their bone binding utility to one of ordinary skill in the art. The skilled artisan would have had a reasonable expectation of success in shaping and using the device of Jones for hard body (bone) implant utilities. *Compare American Standard Inc. v. Pfizer Inc.*, 722 F. Supp. 86, 131, 14 USPQ2d 1673, 1710 (D. Del., 1989) wherein the court found that, as early as 1968-1969, "...the field of biomaterials crossed the orthopedic, dental and cardiovascular specialties, and (2) it was well known at the critical time that soft and bone tissue would grow into pores."

Appellants' arguments regarding the discovery of bone binding properties and a difference in shape of the claimed device versus the device disclosed by Jones have not convinced us of any reversible error in the examiner's rejection of claims 13-19 and 68-106 under 35 U.S.C. § 102/103 as unpatentable over Jones for the reasons set forth above. We note that appellants have not substantiated their arguments with convincing comparative tests showing an actual difference in the shape and/or properties of the claimed device and that of Jones.

Moreover, we do not find the opinions and arguments supplied in the Klaas de Groot declaration convincing for the reasons presented above. We note that the appealed claims are drawn to a prosthetic device *per se*, not a particular use of the prosthetic device. In this regard, the declaration attempts to differentiate appellants' invention from the prior art based on a particular use of the prosthetic device in binding to a hydroxyapatite portion of bone and on the capability of the device to induce the formation of a calcium phosphate layer or deposit calcium, all of which are not required by the claims. *See In re Self*, 671 F.2d 1344, 1350-1351, 213 USPQ 1, 7 (CCPA 1982). Indeed, appellants appear to further undercut the de Groot declaration by acknowledging in their specification that the claimed invention is not limited to the theoretical discussion therein regarding how the polymer may bind to bone (specification, pages 2 and 3).

Appellants' additional arguments and the de Groot declaration opinion regarding Jones teaching away from the claimed bone binding properties by teaching surface energy matching are likewise unconvincing for the reasons discussed above and since the claims do not require a specific bone binding mechanism but rather a prosthetic device that could be fastened

to bone by a variety of techniques unrelated to those discussed by de Groot.

Upon consideration of the evidence and arguments presented, we find ourselves in agreement with the examiner's position. Accordingly, we will sustain the examiner's rejection of claims 13-19 and 68-106 under 35 U.S.C. § 102 as anticipated by Jones or, in the alternative, under 35 U.S.C. § 103 as being unpatentable over Jones.

§ 103 rejection of claim 107 over Jones *in view of Spector*

In addition to having a shape that is suitable for placing the prosthetic device in contact with bone for binding thereto as discussed above, claim 107 additionally requires that the prosthetic device includes a polymer having a porous surface including at least some pores having a diameter within the range of 50 to 500 microns. According to the examiner, it would have been *prima facie* obvious to one of ordinary skill in the art to include pores having a diameter within the claimed range in the polymer material of the device of Jones in view of Spector teaching that the provision of pore sizes overlapping those claimed in a prosthetic device is conducive to the ingrowth of tissue including "cancellous and cortical bone spicules" (column 4, lines 24-53). In this regard, the examiner notes, in effect,

that a skilled artisan would have had ample motivation to employ such pore sizes in Jones since Jones suggests using a net form for the prosthetic material for tissue ingrowth (column 2, lines 36-40 and Example 11). We agree.

We are not convinced by appellants' additional arguments[3] of a lack of a reasonable expectation of success in using pore sizes as claimed in Jones from the combined teachings of Jones and Spector. In this regard, for the reasons indicated *supra* regarding Jones, we do not share appellants' viewpoint regarding the incompatibility of the references' teachings based on the prosthetics of Jones being allegedly only useful for soft tissue applications and the teachings of Spector being only applicable to hard tissue prosthetics as well as their different material compositions. The claimed prosthetic at issue herein is not limited to bone binding applications and the prosthetics of Jones would not have been viewed by a skilled artisan as being limited to soft tissue applications for reasons as generally discussed above. *See American Standard, supra*. Moreover, appellants have not substantiated their argument with objective tests showing

[3]The arguments and evidence advanced above regarding the rejections of claims 13-19 and 68-106 under 35 U.S.C. §§ 102/103 over Jones are not found convincing with respect to the § 103 rejection of claim 107 for the reasons set forth above.

such incompatibility based on differences in prosthetic composition or potential uses thereof.

Accordingly, we agree with the examiner's legal conclusion that the subject matter defined by claim 107 would have been obvious within the meaning of 35 U.S.C. § 103 from the combined teachings of Jones and Spector.

CONCLUSION

To summarize, the decision of the examiner to reject claims 71-106 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as their invention is reversed. The decision of the examiner to reject claims 13-19 and 68-106 under 35 U.S.C. § 102 as anticipated by Jones or, in the alternative, under 35 U.S.C. § 103 as being unpatentable over Jones and to reject claim 107 under 35 U.S.C. § 103 as being unpatentable over Jones in view of Spector is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

CHUNG K. PAK Administrative Patent Judge	)
TERRY J. OWENS Administrative Patent Judge	) BOARD OF PATENT APPEALS AND INTERFERENCES
PETER F. KRATZ Administrative Patent Judge	)

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